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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT APPLICATION EXAMINING OPERATIONS

In re the Application of :  
Sharon F. Kleyne : Group Art Unit: 1617  
Serial No. 09/614,790 : Examiner: Michael Willis  
Filed: July 12, 2000 : Tel. No. (703) 305-1679  
For a Patent for : Date: January 13, 2003  
METHOD AND KIT FOR MOISTURIZING  
THE SURFACE OF THE EYE

**APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §1.193(b)**

Assistant Commissioner for Patents  
Washington, DC 20231

Dear Sir,

This Reply Brief is in response to the Examiner's Answer mailed on November 12, 2002.

This brief is transmitted in triplicate. The following numbers relate to the numbering of the sections in the Examiner's Answer and in Appellant's Brief filed on September 24, 2002.

1 to 6. No response to the Examiner's Answer is necessary.

7. Grouping of Claims

In Section VII of Appellant's Brief, Appellant indicated that claims 75-77 stand together, claim 78 stands alone, claims 79-81 stand together, and claim 82 stands alone. Appellant understands the Examiner's Answer to indicate that the Examiner agrees that claims

75-77 stand independent from claims 79-81, but that Appellant has provided insufficient reasons why claim 78 stands alone from claims 75-77 and why claim 82 stands alone from claims 79-81.

Each of claims 78 and 82 call for an average droplet size of less than 20 microns in diameter. This is a separate patentable distinction because the prior art discloses only droplet sizes as small as 20 microns and is therefore a separate basis of patentability for these claims. This distinction is discussed on page 21 of Appellant's Brief. Appellant submits that the presence of this separate basis of patentability, as discussed in Appellant's Brief, provides sufficient reason why claims 78 and 82 stand or fall by themselves.

8-10. No response to the Examiner's Answer is necessary.

11. Reply to Examiner's Response to Appellant's Arguments

(A) Neither Embleton nor Laibovitz disclose methods for moisturizing the surface of the eye. Rather, each of these references disclose an apparatus that is used to deliver small amounts of a therapeutic compound to the eye. As disclosed in Embleton, on page 13, line 6, such therapeutic compound may include "Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oil . . ."

Appellant has argued that neither Embleton nor Laibovitz discloses that dry eye can be successfully treated by application of essentially water. Dr. Rachael Garrett has submitted a Declaration on behalf of Appellant in which she declares that "Artificial tears, dry eye therapies, and comfort drops contain ingredients other than water that are essential for their beneficial effects" and that one skilled in the art would understand the disclosure of Embleton to mean

"artificial tear/dry eye therapies and comfort drops that are based upon saline, water or oil, and which include other ingredients that are necessarily present in these formulations."

The Examiner has responded to this by providing two U.S. patent references, Ogura (5,307,095) and Scheiner (5,627,611) which purportedly disclose that water is known in the art as an agent for dry eye therapy. Neither of these references, however, disclose the application of water to the surface of the eye. Rather, each of these references discloses an apparatus for maintaining a high-humidity environment surrounding the eye. Appellant submits that such a result could be achieved by a person who sits for an extensive period of time in a steam room. Ogura and Scheiner have disclosed apparatuses that provide the same high humidity as found in a steam room but which high humidity level is limited to the eye, rather than to the entire body. Thus, the prior art does not disclose the *application* of a fluid consisting essentially of water for moisturizing the surface of the eye.

The Examiner has cited MPEP 2111.03 as support for his contention that "consisting essentially of" in the present claims is correctly construed as equivalent to "comprising". Appellant submits that the Examiner's contention is incorrect.

The specification discloses that, in accordance with the invention, an amount of an aqueous fluid is applied to the surface of the eye, which amount is sufficient to rehydrate the aqueous layer of the tear film but which amount does not wash away the tear film. The specification further discloses that present day methods of moisturizing the eye, such as application of eye drops, wash away the tear film and replace it with an aqueous solutions that lack the structure of the intact tear film and replaces it with a fluid that differs from the normal aqueous layer of the tear film.

As taught in the specification, dry eye therapeutic agents other than water, which agents contain constituents that differ from constituents normally present in the tear film, are undesirable for the purpose of moisturizing the surface of the eye. It is clear from the specification and knowledge of those skilled in the art what such agents are. In the Declaration 1 of Dr. Rachael Garrett, she states that such agents include tonicity agents, viscosity increasing agents, wetting agents, preservatives, and antioxidants. Even though such agents may be irritating to the eye, they are necessary when moisturizing the eye by prior art methods which replace the tear film, or the aqueous layer of the tear film, with a moisturizing agent. But, as taught in the specification, the method of the invention permits moisturizing the eye essentially without the use of such agents.

Appellant submits that the specification discloses how such additional components would materially change the characteristics of Appellant's invention, as required by MPEP 2111.03.<sup>1</sup>

Thus, Appellant submits that the claims, which call for a method for moisturizing the surface of the eye and which method includes administering an aqueous formulation consisting essentially of water, patentably distinguish over the prior art.

(B) With respect to claims 79-82, the Examiner continues to insist that a "mist", as called for in claims 79-82 is consistent with a "jet or stream" as disclosed by the prior art

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<sup>1</sup> The specification further discloses a method for application to the surface of the of an aqueous fluid containing a therapeutic medication. This method, which is not covered by the present claims, is not intended to rehydrate the existing aqueous layer of the tear film. Therefore, this method includes the application of an aqueous fluid that does not consist essentially of water, which fluid contains a therapeutic medication and may, of course, contain other desirable agents such as tonicity, viscosity, wetting, preservative, antioxidant agents or other constituents.

Embleton reference. To bolster his assertion, the Examiner cites Appellant's proffered definition of "mist" which includes the following:

a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief. . .* (emphasis in the original).

Appellant submits that one may be able to direct a mist of perfume onto a handkerchief. However, one is not able to direct a mist onto a specified target of the eye, as disclosed by Embleton in reference to a jet or stream. Embleton discloses, on page 3, lines 6-10, that:

The jet or stream can be directed or targeted at a chosen site in an eye; eg, cornea, anterior bulbar conjunctiva, posterior bulbar conjunctiva or palpebral conjunctiva where the active compound can be readily absorbed.

Appellant further submits that, contrary to the Examiner's assertion on page 6 of his Answer, Embleton's use of "jet or stream" of droplets is not at all consistent with a mist, such as that sprayed from a perfume bottle. Such a mist does not have the specificity of directionality as does the jet or stream of Embleton.

Thus, Appellant submits that Embleton does not disclose a mist, and moreover that Embleton teaches away from a mist, as stated in Appellant's Brief.

Additionally, Appellant submits that Laibovitz does not disclose a mist and, even if Laibovitz can be construed as disclosing a mist, it is improper to combine this disclosure with that of Embleton because of Embleton's teaching away from a mist.

Laibovitz discloses drops of the size as those found in a mist. This disclosure of Laibovitz is in a section (column 3, lines 21-28) in which Laibovitz discloses the size of the droplets, not the form in which such droplets are delivered. It is possible to deliver droplets in a

mist or in a jet or stream of droplets. By necessity, in order to be a mist, the droplets must be of a certain small size. A jet or stream likewise may be of droplets of such small size. Appellant submits that Laibovitz's disclosure of such droplet sizes does not indicate that the drops are delivered as a mist, but rather that such droplets are of mist-droplet size. Because the droplets of Laibovitz are delivered to a desired site, see column 3, lines 17-19, the device of Laibovitz is understood to produce a jet or stream of droplets, which droplets are of very small size, that is of a size that would be found in a mist..

Accordingly, Appellant submits that the claims calling for a mist distinguish over the cited prior art, not only because the prior art does not disclose the use of a mist for moisturizing the surface of the eye but also because the combination of the Embleton reference (teaches away from a mist) with the Laibovitz reference (droplets the size found in a mist) is improper.

## CONCLUSION

For these reasons, Appellant respectfully submits that the Examiner has improperly rejected the claims over the disclosure of the prior art and requests that the claims be found to be patentable.

Respectfully submitted,

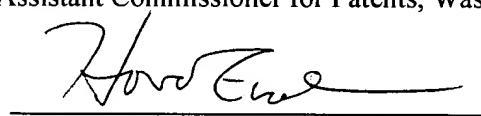


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Attorney for Applicant

## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on January 13, 2003.

Dated: 1/13/03



Howard M. Eisenberg



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# FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

Applicant claims small entity status. See 37CFR 1.27

**TOTAL AMOUNT OF PAYMENT**

**\$0**

Complete If Known	
Application Number	09/614,790
Filing Date	July 12, 2000
First Named Inventor	Sharon F. Kleyne
Examiner Name	Michael Willis
Art Unit	1617

**Attorney Docket No.**

**HME/7982.001**

#### METHOD OF PAYMENT (check all that apply)

Check  Credit Card  Money Order  Other  None

Deposit Account

Deposit Account Number

**50-1773**

Deposit Account Name

Howard Eisenberg

The Commissioner is authorized to: (check all that apply)

- Charge fees indicated below  Credit any overpayments  
 Charge any additional fee(s) during the pendency of this application  
 Charge any fee(s) indicated below, except for the filing fee to the above-identified deposit account.

#### FEE CALCULATION

##### 1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Code (\$)	Code (\$)		
1001 740	2001 370	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 510	2003 255	Plant filing fee	
1004 740	2004 370	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
<b>SUBTOTAL (1)</b>			<b>\$0</b>

##### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims		Fee from below	Fee Paid
	-20**	= 0 x		
Indep. Claims				
Multiple Dependent				

Large Entity	Small Entity	Fee Description
Fee Code (\$)	Fee Code (\$)	
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	**Reissue independent claims over original patent
1205 18	2205 9	*Reissue claims in excess of 20 and over original patent
<b>SUBTOTAL (2)</b>		<b>\$0</b>

\*or number of previously paid, if greater. For reissues, see below.

#### FEE CALCULATION (continued)

##### 3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge-late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1840*	1805 1840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 400	2252 200	Extension for reply within second month	
1253 920	2253 460	Extension for reply within third month	
1254 1,440	2254 720	Extension for reply within fourth month	
1255 1,960	2255 980	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,280	2453 640	Petition to revive - unintentional	
1501 1,280	2501 640	Utility issue fee (or reissue)	
1502 460	2502 230	Design issue fee	
1503 620	2503 310	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt.	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 740	2809 370	Filing a submission after final rejection (37 C.F.R. 1.129(a))	
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	
1801 740	2801 370	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	
Other fee (specify)			
* Reduced by Basic Filing Fee Paid		<b>SUBTOTAL (3)</b>	<b>\$0</b>

SUBMITTED BY		Complete (if applicable)		
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Signature		Date	January 13, 2003	

TRANSMITTAL  
FORM

(to be used for all correspondence after initial filing)

Application Number 09/614,790

Filing Date July 12, 2000

First Named Inventor Kleyne, Sharon

Group Art Unit 1617

Examiner Name Michael Willis

Total Number of Pages in this Submission

23

Attorney Docket Number HME/7982.001

- Fee Transmittal Form  
 Fee Attached
- Amendment/Response  
 After Final
- Affidavit(s)/Declaration(s)
- Extension of Time Request
- Express Abandonment Request
- Information Disclosure Statement
- Certified Copy of Priority Document(s)
- Response to Missing Part(s)/Incomplete Application  
 Response to Missing Parts under 37CFR 1.52 or 1.53

- Assignment Papers (for an application)
- Drawings
- Licensing-related Papers
- Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- Petition To Convert to a Provisional Application
- Power of Attorney, Revocation, Change of Correspondence Address
- Terminal Disclaimer
- Small Entity Statement
- Request for Refund

- After Allowance Communication to Group
- Appeal Communication to Board of Appeals and Interferences (Reply Brief - in triplicate)
- Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
- Proprietary Information
- Status Letter
- Additional Enclosure(s) (please identify below)

Remarks:

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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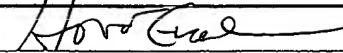
Signature 

Date January 13, 2003

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Signature  Date January 13, 2003

